Thermo
ELECTRON CORPORATION

MAR 1 2 2007

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: k063647

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Electron Oy
Address:	Ratastie 2 P.O. Box 100 FIN-01621 Vantaa Finland
Phone:	+358 (9) 329 100 tel
Fax:	+358 (9) 3291 0500 fax
Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	December 05, 2006

C. Device name

Proprietary name:	CYSTATIN C, (code 981911)
Common name:	Cystatin C
Classification:	Clinical Chemistry
Class:	II
Product Code:	NDY
Regulation Number	21CFR 862.1225

Proprietary name:	CYSTATIN C CALIBRATOR, (code 981912)
Common Name:	Calibrator
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIT
Regulation Number	21CFR 862.1150

Proprietary name:	CYSTATIN C CONTROL, (code 981913)
Common Name:	Control (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJX
Regulation Number	21CFR 862.1660

Proprietary name:	CYSTATIN C CONTROL HIGH, (code 981914)
Common Name:	Control (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJX
Regulation Number	21CFR 862.1660

D. Intended Use

CYSTATIN C

For in vitro diagnostic use in the quantitative determination of the Cystatin C concentration in human serum, Li-heparin plasma and EDTA plasma on T60 analyzers.

CYSTATIN C CALIBRATOR

Cystatin C Calibrator is intended for *in vitro* diagnostic use on T60 analyzer. Cystatin C Calibrator is used as a calibrator for quantification of Cystatin C in serum and plasma by immunoturbidimetry using methods defined by Thermo Electron Oy

CYSTATIN C CONTROL

Cystatin C Control is intended for in vitro diagnostic use on T60 analyzer. Cystatin C Control is used as a quality control to monitor precision of the Cystatin C test using methods defined by Thermo Electron Oy.

CYSTATIN C CONTROL HIGH

Cystatin C Control High is intended for *in vitro* diagnostic use on T60 analyzer. Cystatin C Control High is used as a quality control serum to monitor precision of the Cystatin C test using methods defined by Thermo Electron Oy

E. Indications for use

The Cystatin C is intended for quantitative in-vitro diagnostic determination of Cystatin C in human serum or Li-heparin plasma and EDTA plasma using T60 Clinical Chemistry Analyzers.
Cystatin C measurements in serum and plasma are used as an aid in the diagnosis and treatment of renal diseases.

For Cystatin C Calibrator, Cystatin C Control and Cystatin C Control High, see intended use

F. Substantial Equivalence

The Cystatin C is substantially equivalent to the Dako Cystatin C reagent (K041627) with respect to indications for use, device design, materials and operational principles. The basic differences between the new device and Dako predicate device are the instruments used for testing. The Dako device can be used on commercially available turbidimetry and nephelometry analyzers, while the T60 device can be used on only T60 analyzers.

G. Substantial equivalence -similarities

Cystatin C is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Dako Cystatin C test.

Thermo Electron Oy
Ratastie 2
P.O. Box 100
FIN-01621 Vantaa
Finland
+358 (9) 329 100 tel
+358 (9) 3291 0500 fax
Y-tunnus 0921547-0
VAT No FI09215470
Domicile Helsinki
www.thermo.com

The following table compares the Cystatin C with the predicate device.

Table 1

Attribute	**New device #1**	**Predicate device #1**
Intented Use	For *in vitro* diagnostic use in the quantitative determination of the Cystatin C concentration in human serum, Li-heparin plasma and EDTA plasma on T60 analyzer.	Cystatin C Immunoparticles are intended for the quantitative determination of cystatin C in human serum, heparinized plasma and EDTA plasma by turbidimetry and nephelometry. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.
Indication for Use	Cystatin C is intended for quantitative in-vitro diagnostic determination of Cystatin C in human serum or Li-heparin plasma and EDTA plasma using T60 Clinical Chemistry Analyzers. Cystatin C measurements in serum and plasma are used as an aid in the diagnosis and treatment of renal diseases.	Cystatin C Immunoparticles are intended for the quantitative determination of cystatin C in human serum, heparinized plasma and EDTA plasma by turbidimetry and nephelometry. Cystatin C measurements are used as an aid in diagnosis and treatment of renal diseases.
Assay Protocol	Particle enhanced immunoturbidimetric	Particle enhanced immunoturbidimetric
Traceability/Standardization	The value of Cystatin C has been assigned by using a precise transfer protocol ensuring traceability to a pure recombinant Cystatin C preparation, where the Cystatin C concentration was established by dry mass determination.	The value of Cystatin C has been assigned by using a precise transfer protocol ensuring traceability to a pure recombinant Cystatin C preparation, where the Cystatin C concentration was established by dry mass determination.
Sample Type	Human serum, Li-heparin plasma and EDTA plasma	Human serum, heparinized plasma and EDTA plasma
Reagent Storage	Store at 2°C - 8°C.	Store at 2°C - 8°C.
Expected Values	Individuals 1-50 years of age: 0.55-1.15 mg/L Individuals >50 years of age: 0.63-1.44 mg/L	Individuals 1-50 years of age: 0.55-1.15 mg/L Individuals >50 years of age: 0.63-1.44 mg/L
Instrument	T60 and DPC T60i, DPC T60i Kusti	Hitachi 911, Hitachi 917, Cobas Mira Plus and IMMAGE
Measuring Range	0.44 – 7.0 mg/L	~0.4-7.5 mg/L

Attribute	New device #1	Predicate device #1
Precision	**Within run** Level 0.70 mg/L SD = 0.010 CV(%) = 1.4 Level 1.49 mg/L SD = 0.039 CV(%) = 2.6 Cystatin C Control 1.03 mg/L SD = 0.028 CV(%) = 2.7 Cystatin C High Control 4.59 mg/L SD = 0.054 CV(%) = 1.2 **Between run** Level 0.70 mg/L SD = 0.011 CV(%) = 1.5 Level 1.49 mg/L SD = 0.006 CV(%) = 0.4 Cystatin C Control 1.03 mg/L SD = 0.032 CV(%) = 3.1 Cystatin C High Control 4.59 mg/L SD = 0.038 CV(%) = 0.8 **Total** Level 0.70 mg/L SD = 0.016 CV(%) = 2.3 Level 1.49 mg/L SD = 0.038 CV(%) = 2.6 Cystatin C Control 1.03 mg/L SD = 0.044 CV(%) = 4.2 Cystatin C High Control 4.59 mg/L SD = 0.074 CV(%) = 1.6	**Results obtained on Hitachi 917 following the NCCLS EP5-A** **Total** Cystatin C Control 1 CV(%) = 2.1 Cystatin C Control 2 CV(%) = 2.6 Human Serum Pool Low CV(%) = 5.9 Human Serum Pool Medium CV(%) = 2.0 Human Serum Pool High CV(%) = 2.3

Attribute	New device #1	Predicate device #1
Method Comparison	y = 0.94x + 0.091 r = 0.9988 Range 0.21 to 6.58 mg/L n = 54	**Dade Behring N Latex Cystatin C Test Kit** **Dade Behring Prospec Nephelometer** Heparinized plasma samples: y = 0.6954x + 0.214 r = 0.9865 n = 190
Limitations	**Lipemia:** No interference found up to 800 mg/dL of Intralipid™ (trademark of Fresenius Kabi AB) No interference found up to 1500 mg/dL of triglycerides **Hemoglobin:** No interference found up to 1000 mg/dl of hemoglobin in hemolysate **Bilirubin, conjugated:** No interference found up to 58.5 mg/dl of conjugated bilirubin **Bilirubin, unconjugated:** No interference found up to 58.5 mg/dl of unconjugated bilirubin **Rheumatoid factor:** No interference was found up to 1200 IU/mL	**Triglyceride** No interference was found for triglyceride up to 15 g/L (1500 mg/dL) **Hemoglobin** No interference was found for hemoglobin up to 10 g/L (1000 mg/dL) **Bilirubin, conjugated** No interference was found for conjugated bilirubin up to 600 mg/L (60 mg/dL) **Bilirubin, nonconjugated** No interference was found for nonconjugated bilirubin up to 600 mg/L (60 mg/dL) **Rheumatoid factor** No interference was found for rheumatoid factor up to 1200 IU/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Paivi Sormunen
Thermo Electron Oy
Ratastie 2
P.O. Box 100
Vantaa 01621
Finland

MAR 12 2007

Re: k063647
Trade/Device Name: Cystatin c antiserum, calibrator, control and control high
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: NDY, JJX, JIT
Dated: December 05, 2006
Received: December 15, 2006

Dear Mr. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k063647

Device Names: **Cystatin C**
Cystatin C calibrator
Cystatin C control
Cystatin C Control High

Indications for Use:
Cystatin C is intended for quantitative in-vitro diagnostic determination of Cystatin C in human serum or Li-heparin plasma and EDTA plasma by turbidimetry using T60 Clinical Chemistry Analyzers.
Cystatin C measurements in serum and plasma are used as an aid in the diagnosis and treatment of renal diseases.

Cystatin C Calibrator is intended for *in vitro* diagnostic use on T60 analyzer.
Cystatin C Calibrator is used as a calibrator for quantification of Cystatin C in serum and plasma by immunoturbidimetry using methods defined by Thermo Electron Oy.

Cystatin C Control is intended for in vitro diagnostic use on T60 analyzer.
Cystatin C Control is used as a quality control to monitor precision of the Cystatin C test using methods defined by Thermo Electron Oy.

Cystatin C Control High is intended for *in vitro* diagnostic use on T60 analyzer.
Cystatin C Control High is used as a quality control serum to monitor precision of the Cystatin C test using methods defined by Thermo Electron Oy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Page 1 of 1

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
(Optional) K063647